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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,489	ILAN ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/04/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,15-17,20-24,63 and 64* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 15-17, 20, 22-24 and 63-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/04/2009 has been entered.

Status of Claims

2. Claims 1-11, 13-14, 18-19 and 25-62 are cancelled. Claims 12, 15-17, 20-24 and 63-64 are pending. Claim 21 is withdrawn for being directed to a non-elected invention, which is HCV. Claims 12, 15-17, 20, 22-24 and 63-64 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12, 15-17, 20, 22-24 and 63-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the rejection, Applicant continues to argue that the claimed invention is enabled. Applicant argues that the mere fact that experimentation might be required is insufficient to support an enablement rejection and that even complex experimentation is not necessarily undue. Applicant reminds the Office of the eight Wands factors in determining enablement, and note that it is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. Applicant also directs the Office attention to line 24, page 14 to line 16, page 15 of the specification to evidence that the specification teaches that the administration of glycolipids/glycosylceramides treat HCV. Applicant also points to line 3, page 9 to line 3, page 13 and lines 18-23, page 17 to demonstrate that the specification describes experimental results showing that glycolipids cause a change in the immune profile of subject.

Applicant's response has been considered, however, it is not found persuasive. The instant enablement rejection is not based on only one of the eight Wands factors. Rather, as indicated in the office action, most, if not all the Wands factors were considered in determining enablement. Thus, Applicant's allegation, while correct, that mere fact that experimentation, even complex experimentation might be required is insufficient to support an enablement for they are not necessarily undue. However, in this case, the lack of enablement for the claimed invention is not solely based on the mere fact that experimentation is required. Nor does the Office consider that the claimed invention is not enabling because it involves complex experimentation. As a whole, the enablement rejection is issued because it is found that the skilled artisan

would not be able to practice the claimed invention without undue experimentation. Such conclusion is made on the basis of the Wands factors.

Regarding the specification, the entire specification, including the passages cited by Applicant in Applicant's traversal of the enablement rejection, were considered in determining enablement. As noted in the record, all Applicant has is nexus among the immune profiles of normal and Gaucher patients that are either infected or uninfected with HCV. Applicant has not demonstrated and evidences that glycolipids itself treats any disease, including HCV. The mere fact that Applicant's specification contains texts that discloses such nexus and concludes, based on the nexus, is not sufficient to support a prima facie case of enablement. While the text of the specification may be used to evidence written description, however, the instant rejection is enablement. The written description requirement is separate and distinct from the enablement requirement. The claimed invention may be described without the disclosure being enabling. In the instant case, while the specification describes the claimed invention, it fails, on the basis of the Wands factors, to enable the claimed invention.

In addition to above, Applicant takes issue with the statements made by the Office in page 6 of the previous office action. The statements include, it is noted that the specification contains neither an in vitro nor an in vivo study demonstrating that glycolipids treat HCV infection, Applicant has not demonstrated that glycolipids treat HCV…etc. Referring to these statements, Applicant argues that the statements concerns issues in evaluating the results of the treatment after carrying out the present invention, rather than the ability of the skilled artisan to use the invention.

Applicant's criticism has been considered, however, it is not found persuasive. Contrary to Applicant's assertion, these statements do not only concern issues in evaluating results of the treatment after carrying out the present invention, rather, these statements are directed at evidencing that the claimed invention is not enabling. In the instant case, the claimed invention is directed to a method of treating HCV with the administration of glycolipids to a subject. Yet, Applicant has failed to demonstrate and evidence that glycolipids treats HCV. As stated, all that Applicant has demonstrated is a nexus among different provides. Based on this nexus, Applicant drew a conclusion that is not substantiated by any data that demonstrates and evidences that the administration of glycolipids treats HCV in a subject. In the instant case, Applicant's claimed invention is merely an invitation for the skilled artisan to blindly experiment, wherein along with the analysis provided based on the Wands factors, the experimentations required of the skilled artisan would be undue.

Applicant also takes issue with the Office's position, as disclosed on pages 5-6 of the previous office action. Applicant argues that practice of the invention does not require an investigation into the particular mechanisms and that the administration of the glycolipid intrinsically causes a series of events that take place for which the practitioner has no further control after administration step. Applicant submits that the lack of knowledge of this mechanism does not hinder the skilled artisan in practicing the claimed invention nor does possession of such information engender any particular increased ability, and notes that the only advantage of having such knowledge would be

the potential increase in confidence by the Examiner that the invention would work as claimed by the inventors.

Applicant's argument has been considered, however, it is not found persuasive. Applicant is reminded that the establishment of enablement or lack thereof is not based on the Office's confidence that the claimed invention would or would not work. Determination of enablement is based on the Wands factors, which the Office has and continues to use to establish that the claimed invention is not enabling. In the instant case, the Office's position is that the claimed invention is an invitation to the skilled artisan practicing the claimed invention to blindly experiment for Applicant has not disclosed anything more than a nexus among immune profiles.

As presented in the 03/04/2009 office action, in response to the enablement rejection, Applicant continues to argue that the claimed invention is enabling. Applicant argues that Applicant "clearly teaches the administration of glycolipids for the treatment of HCV infection". To support Applicant's argument, Applicant submits that Applicant has discovered that patients with high glycolipids levels, characteristic of Gaucher's disease, have reduced autoimmune responses generated by HCV infections. Applicant also criticizes the Office for it appears to Applicant that the Office is equating "treatment" with the term "cure". Applicant argues that the administration of the glycolipids is a "treatment" (an action) regardless of what results take place. Applicant also reminded the Office that the claimed invention is not directed at all diseases, but limited to cancer, a viral infection or an autoimmune disease. Applicant additionally asserts that the Office has failed to offer any evidence that the claimed method will not work. Applicant further

argues that the absence of the innate and antigen-nonspecific immune responses to HCV does not prevent one of skill in the art from having the ability t administer glycolipids for the treatment of HCV. Applicant additionally submits that a lack of in vitro studies and animal models with regard to HCV research has not eliminated development in the area. To support this point, Applicant cited several references to demonstrate that suitable in vitro and in vivo assays are available to the skilled artisan at the time of the present filing. Applicant further asserts that the only requirement that would be needed to practice the claimed invention is to establish the route of administration and treatment dosage amounts.

Applicant's arguments have been considered, however, none are found persuasive. Contrary to Applicant's assertion that Applicant "clearly teaches the administration of glycolipids for the treatment of HCV infection", no such teaching can be found in the specification. The specification does not clearly teach or demonstrate that the administration of glycolipids treats HCV infection. The specification does not contain any working examples evidencing to the skilled artisan that the administration of glycolipids treats HCV infection.

It appears that Applicant has misconstrued the rejection as a written description rejection. Applicant is reminded that the written description requirement is severable from the enablement requirement. Had the Office had any doubt about the adequacy of the written disclosure for the claimed invention, a written description rejection would be issued and maintained.

Regarding Applicant's discovery, it should be noted that the Office does not doubt or question Applicant's discovery. However, in following the Wands factors, it is found that such discovery is not sufficient to enable the skilled artisan to practice the claimed invention without undue experimentation. Applicant's discovery is limited to the finding of a nexus or association between Gaucher's disease and HCV, as admitted by Applicant in Applicant's response. Such discovery does not commensurate in scope with the claimed invention, a method for treating HCV infection in HCV infected subjects. As noted in the office action and throughout the examination process, Applicant has not demonstrated nor evidenced that the administration of glycolipids treats HCV.

Additionally, contrary to Applicant's assertion, the Office is not equating treatment with cure. Had the Office equated treatment with cure, the Office would have readily included such interpretation in determining the breadth of the claims and nature of the claimed invention, which are two of the Wands factors used in determining lack of enablement.

Regarding Applicant's interpretation of "treatment", such has been noted, However, Applicant is reminded that the claims clearly recite a method treating a disease. Applicant's reminder to the Office is clearly noted, however, it should be noted that the enablement rejection is clearly directed at a method of treating HCV infection.

Regarding Applicant's assertion that the Office has failed to offer any evidence that the claimed invention will not work, Applicant is reminded that enablement is not directed at establishing that a claimed invention will not work. Rather it is directed at

establishing if the skilled artisan would be able to practice the claimed invention without undue experimentation, wherein the Wands factors are used to determine a lack of enablement. In the instant case, through the Wands factors, the claimed invention has clearly been determined to not be enabling. That is, the skilled artisan would not be able to practice the claimed invention without undue experimentation.

As noted in the previous office action, innate and antigen-specific immune responses to HCV are not completely characterized. While this lack of knowledge does not prevent one of skill in the art to administer glycolipids to a subject, however, this lack of knowledge contributes to the challenges that the skilled artisan would encounter in attempting to practice the claimed invention, administering glycolipids to treat HCV infections. Thus, while Applicant is correct to note that the absence of such knowledge does not and should not prevent one of skill in the art to administer glycolipids, the Office finds that, along with the other Wands factors, the absence contributes to the undue experimentation the skilled artisan would have in practicing the claimed invention.

Additionally, as Applicant submits, while the lack of in vitro studies and animal models do not eliminate development in HCV research, however, such absence contributes to the challenges that the skilled artisan practicing the claimed invention would encounter. The noted challenges would thereby contribute to the undue experimentation said artisan would have to conduct in attempting to practice the claimed invention. Moreover, it is noted that the specification contains neither an in vitro

nor an in vivo study demonstrating that glycolipids treat HCV infection. All that is present, as noted, is an association study between HCV and Gaucher's disease.

And, contrary to Applicant's assertion, route of administration and treatment dosages are not the only requirement for the skilled artisan to practice the claimed invention without undue experimentation. Applicant has not demonstrated that glycolipids treat HCV. Thus, for a skilled artisan to practice the claimed invention, the skilled artisan would have to demonstrate that glycolipids treats HCV, something that Applicant should have all ready provided in Applicant's disclosure. As established in the office action, using the Wands factors, the skilled artisan would not be able to demonstrate that glycolipids treat HCV without undue experimentation.

Thus, in view of the discussion above, the claims remain rejected for the reasons of record.

Applicant additionally submits that a lack of in vitro studies and animal models with regard to HCV research has not eliminated in the area. To support this point, Applicant cited several references to demonstrate that suitable in vitro and in vivo assays are available to the skilled artisan at the time of the present filing.

As presented in the 06/17/2008 office action, in response to the rejection, Applicant alleges that the Office has misconstrued the claimed invention and the enablement standard, and that the claimed invention is enabling. Applicant specifically argues that the test of enablement is not whether any experimentation is necessary but whether if experimentation is undue.

Applicant's arguments have been considered, however, they are not found persuasive. Applicant's reference to the test of enablement is correct. The test of enablement is whether one of skill in the art would be able to make and use the claimed invention without undue experimentation. In the instant case, using the Wands Factors, a prima facie case of undue experimentation has clearly been established by the Office in the enablement rejection. As noted in the enablement rejection, the elected invention for examination is a method of treating HCV in a mammal with the administration of a glycolipid. Yet, it is noted that Applicant has not taught nor demonstrated to the skilled artisan that the administration of any glycolipids treats HCV. All Applicant has demonstrated is an association between Gaucher's disease and hepatitis C virus infection. In the specification, Applicant notes that subjects diagnosed with Gaucher's disease and HCV infection have an immune profile that is different from those diagnosed with only Gaucher's disease, all of which is summarized in Figures 1-6 in the specification. Specifically, Applicant notes the following: i) HCV specific T cell proliferation and the percent of peripheral natural killer T lymphocytes are less in subjects diagnosed with both Gaucher's disease and HCV infection compared to those diagnosed with only Gaucher's diseases; and ii) the level of interferon gamma, interluekin-10 and interleukin 4 observed in subjects diagnosed with both Gaucher's disease and HCV are higher than those diagnosed with only Gaucher's diseases. In the instant, at the very best, the specification sets forth a nexus among various immune parameters, HCV and Gaucher's disease. The specification does not set forth any guidance or direction that would bridge the gap between the observations made by

Applicant in the specification and the claimed invention, treating HCV with the glycolipid. There is no information provided in the specification detailing the type of immune parameter that should be modulated to treat HCV or any disease. There is no information provided in the specification regarding the specific immune parameter that a particular metabolite/glycolipid modulates and how the modulation results in the treatment of HCV. No such information or guidance is provided in the specification. While it is noted that Applicant submitted that pages 13-15 of the specification offers guidance to those skilled in the art with regard to both the specific compounds as well as specific disease to be treated with the claimed invention; however, it should be noted that theses are merely assertions or suggestions of use. The note disclosure is insufficient to enable the skilled artisan to practice the claimed invention without undue experimentation. In the instant case, the skilled artisan cannot rely on the disclosure set forth in the specification to reasonably practice the claimed invention without undue experimentation.

Regarding Applicant's allegation that the Office has misconstrued Applicant' claimed invention. Contrary to Applicant's assertion, such does not exist. In the instant case, the Office correctly construed the claimed invention. The claimed invention is directed to a method of treating HCV. From Applicant's disclosure, it is deduced that the nature of the claimed invention is directed at modulating the immune response in an individual with glycolipids to treat HCV. The desired immune response is a Th1 immune response, as detailed in the IFN-gamma data charted in the specification. Thus, contrary to Applicant's assertion, the Office has not misconstrued the claimed invention.

Additionally, it should be noted that while the absence of any teachings relating to a mechanism of action does not necessary render the claimed invention not enabling, such absence does not further enable the claimed invention when evaluated as a whole using the Wands Factors.

Additionally, as noted above, Applicant teaches that metabolites such as glycolipids modulate the immune profile, however, such does not commensurate with the claimed invention. The claimed invention is not directed at a method of modulating an immune response in an HCV infected person. Rather, the claimed invention is directed at a method of treating HCV in an HCV infected person. Thus, to be enabling for the claimed invention, Applicant must demonstrate that the skilled artisan would be able to practice the claimed invention without undue experimentation. In the instant case, as discussed above and communicated in the rejection, Applicant has failed to provide an enabling disclosure.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Nature of the invention:

The claimed invention is directed at the treatment/treating of diseases, wherein the elected disease is hepatitis C virus, HCV, with the administration of a glycolipid. As noted by Applicant, the claimed invention relates to the application of glycolipid to regulate and manipulate immune responses, Th1 and Th2 responses, in mammalian subjects to treat mammalian subjects of an infection, particularly wherein the elected infection is hepatitis C virus. [First paragraph, Field of the invention, page 1 of specification.]

Breadth of the claims:

The claims encompass all cancer, viral infections or autoimmune diseases, **wherein the elected disease is hepatitis C virus**; all mammalian subjects, and glycolipids.

Presence or absence of working examples and Amount of direction or guidance presented:

The specification does not contain any working examples demonstrating the effective use of glycolipids to treat HCV infection. All that is present in the specification is an association study, which demonstrates that HCV infected subjects have a different immune profile if they are also diagnosed with Guacher's disease, compared to those

that are not diagnosed with Guacher's disease, where there is a buildup of glucosylcerebroside (glycolipid) due to the decreased capacity for breakdown of this product. Through this association study, Applicant suggests the administration of glycolipds to treat HCV infection by modulating a change in at least one immune component. [Paragraph bridging pages 12-13, in particular.] However, Applicant has not set forth any guidance or direction relating to the immune component that must be changed or modulated in order to render treatment to HCV infected subjects. What is the immune component that must be modulated or changed? Is it a Th1 or Th2 immune response that must be induced? What kind of Th1 or Th2 induced cytokines must be produced in order to effective treat HCV? Is this modulation or change is directed at increasing or decreasing the activity of this particular immune component? And are glycolipids capable of rendering this change or modulation? In the instant case, beyond the speculative use of glycolipids to treat HCV, Applicant has not provided any additional information or evidence regarding the effective use of glycolipids to treat HCV infection.

State of the prior art:

The hepatitis C virus (HCV) art clearly notes that the role of innate and antigen-nonspecific immune response to HCV has not yet been sufficiently characterized.[1] In the absence of a sufficient characterization of the role of innate and antigen-nonspecific immune responses to HCV, the skilled artisan would not readily be able to practice the claimed invention without an undue burden of experimentation. In the absence of such

characterization, the burden is on the skilled artisan to mine the field to determine significance of the innate and antigen-nonspecific in HCV treatment. The art additionally acknowledges several factors that challenge the development of an effective treatment for HCV. [2, 3, 4]

The first factor is the lack of an effective cell culture system for HCV. In the absence of an effective cell culture system for HCV, the skilled artisan would be at an automatic disadvantage when it comes researching the effects of innate or antigen-nonspecific immune responses in HCV treatment. The second challenge is the absence of good animal models for HCV, outside of humans and chimpanzees. In the instant case, the noted disadvantage that the skilled artisan would face in practicing the claimed invention is further compound by the noted absence of good animal models for HCV. Combined, in the absence of an effective in vitro and in vivo model for conduct HCV research, a prima facie case of undue experimentation and unpredictability is established. The other challenge is the ability of HCV to evade effective immune recognition, including recognition by cytotoxic T lymphocytes (CTL), and shows an extremely high rate of viral persistence. In the instant case, it should be noted that Applicant has not taught the skilled artisan how to deal or address each of the challenges addressed herein. This last point further establishes that the type of

[1] Knipe DM, Howley PM, eds. Fields virology. 4th ed. Vol. 1. Philadelphia: Lippincott Williams & Wilkins, 2001, 1004-1016 and 1127-1161.
[2] Hahn. Subversion of immune responses by hepatitis C virus: immunomodulatory strategies beyond evasion? Current opinion in Immunology, 2003, Vol. 15, 443-449.
[3] Knipe DM, Howley PM, eds. Fields virology. 4th ed. Vol. 1. Philadelphia: Lippincott Williams & Wilkins, 2001, 1004-1016 and 1127-1161.
[4] De Francesco et al. Challenges and successes in developing new therapies of hepatitis C. Nature, 2005, Vol. 436, 953-960.

experimentation that the skilled artisan would have to perform in practicing the claimed invention is beyond routine experimentation, such as establishing route of administration and treatment dosage amounts. The imposition of experimentations that is beyond routine experimentation would unduly burden the skilled artisan practicing the claimed invention.

Quantity of experimentation necessary:

The skilled artisan cannot rely on the disclosure set forth in the specification to reasonably practice the invention without the burden of undue experimentation. In order for the skilled artisan to successfully practice the claimed invention, the skilled artisan would have to blindly and unduly experiment with glycolipids, each immune component, and determine the relationship among the glycolipids, each immune components and HCV infection.

In all, the skilled artisan practicing the claimed invention would have to bridge the gap between the glycolipids and HCV infection, the gap that should have been substantially filled by Applicant, at the time the invention was filed. In the instant case, the attainment of such knowledge would undeniably be an undoubtedly laborious task that includes both blind and undue experimentations. And the imposition of both blind and undue experimentations would unarguably be an undue burden for the skilled artisan.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the

claimed invention without undue experimentation. In re Wright, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

Conclusion

5. No claims are allowed.

6. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./